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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/714,333

11/14/2003

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EXAMINER

PITRAK, JENNIFER S

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

03/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/714,333 | Applicant(s) KHVOROVA ET AL. | |
| | Examiner JENNIFER PITRAK | Art Unit 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-54,57-60,68,70-77,79,81 and 84-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-54,57-60,68,70-77,79,81 and 84-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Remarks

Applicant's amendments and arguments filed 12/28/2009 have been entered and considered. Claims 43-54, 57-60, 68, 70-77, 79, 81, and 84-87 are pending and are under examination. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicant's arguments regarding support for the length limitation of 19-30 nucleotides is persuasive. Therefore, the claims are afforded priority to the filing date of provisional application, 60/426137, which is 11/14/2002.

Claim Objections - New

Claims 43-54, 57-60, 68, 70-77, 79, 81, and 84-87 are objected to because of the following informalities: claims 43, 68, and 86 recite "said siRNA" and "candidate siRNA" when referring to an "siRNA sequence" or a "candidate siRNA sequence". Therefore, the antecedent basis for "said siRNA" and "candidate siRNA" is not explicit. Appropriate correction is required.

Claim Rejections - 35 USC § 112 ¶ 1 - Withdrawn

The rejection of claims 43-54, 57-60, 68, 70-77, 79, 81, and 84-87 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) is withdrawn. The amendments to the claims have obviated the rejection.

Claim Rejections - 35 USC § 112 ¶ 2 - Withdrawn

The rejection of claims 43-54, 57-60, 68, 70-77, 79, 81, and 84-87 under 35 U.S.C. 112, second paragraph, as being indefinite due to the claims' reference to the antisense strand is withdrawn. The amendments have obviated the rejection.

Claim Rejections - 35 USC § 112 ¶ 2 - New

Claims 43-54, 57-60, 68, 70-77, 79, 81, and 84-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As a first matter, claim 86 recites "the sense region". There is insufficient antecedent basis for this limitation.

As a more general matter, the claims are to methods for obtaining an siRNA molecule by 1) selecting a target gene, 2) identifying a set of candidate siRNA sequences, 3) applying criteria to candidate siRNA sequences, 4) selecting candidate siRNA sequences that satisfy the criteria,

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and 5) synthesizing an siRNA molecule. The only requirements for the siRNA molecules resulting from such methods are those that meet as few as a single criterion such as "a presence of A at position 19 of the sense sequence", for example. The siRNA sequences or siRNA molecules are not identified otherwise such as by sequence identity to the target, for example. The candidate siRNA sequences or candidate siRNAs are not described such that the input (candidates) and output (siRNA molecule for a target gene) of the claimed methods can be readily identified. The relationship, such as complementarity or alignment, of the sense sequence or sense region to the antisense sequence or antisense region or the target is not described such that the resulting siRNA molecule for a target gene can be readily identified.

Claim Rejections - 35 USC § 112 ¶ 1 - New

Claims 43-54, 57-60, 68, 70-77, 79, 81, and 84-87 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of obtaining an siRNA molecule for a target gene wherein the method comprises identifying a set of candidate siRNA sequences comprising a sense sequence having sequence similarity to the target gene or having an antisense sequence with complementarity to the target gene, and applying a computer algorithm to the candidate siRNA sequences, does not reasonably provide enablement for methods of obtaining an siRNA molecule for a target gene wherein the method comprises identifying a set of candidate siRNA sequences comprising any sense sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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The claims are directed to methods for obtaining an siRNA molecule for a target gene wherein candidate siRNA sequences are identified and then screened according to a computer algorithm for specific positional sequence criteria. The claims do not specify how candidate siRNA sequences are identified and do not require that the candidate siRNAs have any sequence similarity or complementarity to the target sequence. The claims, therefore, embrace methods for obtaining an siRNA molecule for a target gene wherein the candidate siRNA sequences have any nucleotide sequence. Those sequences that have, for example, an A at position 19 of the sense sequence, would be selected as an siRNA for the target gene. If such an siRNA with an A at position 19 has no complementarity or similarity to the target gene, then the siRNA molecule obtained by the method would not function as an siRNA to the target gene: it would not inhibit expression of the target gene. Therefore, the claims are clearly not enabled in their full scope.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak
Examiner
Art Unit 1635

/Richard Schnizer/
Primary Examiner, Art Unit 1635